

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 21-R-0173
2. Number 20 of animals used in this study.
3. Species (common name) CATS of animals used in the study.

4. Explain the procedure producing pain and/or distress.

THE ADMINISTRATION OF CHLAMYDIA PSITTACI TO UNVACCINATED CATS
PRODUCING THE CLINICAL SIGNS AND SYMPTOMS OF THE ILLNESS.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

9 CFR SECTION 113.71 OUTLINES REQUIREMENTS TO LICENSE A PRODUCT SUCH AS THAT BEING TESTED IN THIS STUDY. CLINICAL DISEASE MUST BE ALLOWED TO PROVE EFFICIENCY OF THE CHALLENGE DOSE. THIS DOSE WILL IN TURN BE USED IN VACCINE DEVELOPMENT.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency APHIS CFR 9CFR113.71

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1. Registration Number: 21-R-0173
2. Number 60 of animals used in this study.
3. Species (common name) DOGS of animals used in the study.



4. Explain the procedure producing pain and/or distress.

ADMINISTRATION OF AN EXPERIMENTAL VACCINE WAS ACCOMPANIED BY A SEVERE ALLERGIC REACTION IN ONE ANIMAL.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

THE SEVERE ALLERGIC REACTION, IN ONE ANIMAL, WAS AN UNANTICIPATED ADVERSE RESPONSE ACCOMPANYING THE EXPERIMENTAL VACCINE ADMINISTRATION, WHERE THE ANIMAL DIED BEFORE IT COULD BE EUTHANIZED.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency APHIS CFR 9CFR113.40